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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,342	06/25/2003	Guangyang Wang	TIBO-0003(TIP)	4013

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EXAMINER	
OWENS, AMELIA A	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,342	WANG ET AL.	
	Examiner	Art Unit	
	Amelia A. Owens	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 20-21,23-28 and 30-72 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 20-21,23-28,30-72 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 19, 22, 29 have been canceled. Claims 20-21; 23-28, 30-72 are pending.

Claim Rejections - 35 USC § 112

Claims 20, 21, 23-28, 30-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' comments have been considered and the rejection maintained for the following reasons.

The nature of the invention: The claims are drawn to antiretroviral compositions, method treating an infection or disease associated with a retrovirus infection using claimed compounds its ester, prodrugs or metabolites thereof; and a kit for preventing/treating retroviral infections; method of inhibiting retroviral replication; method of inhibiting a protease of a retrovirus. See claims.

The state of the prior art and predictability: In the instant case, the instantly claimed invention is highly unpredictable since treating and/or preventing retrovirals is unpredictable. No combination of compounds has been found effective in treating, preventing, ALL retrovirals. Retrovirals are known to be compound and disease specific, that is particular compounds or classes of compounds are known to be effective against particular retrovirals. Furthermore, applicant has not demonstrated that the claimed composition is successful in treating, preventing, retrovirals; inhibiting retroviral replication; inhibiting a protease of a retrovirus. Applicants are claiming all known retrovirals and retrovirals yet to be discovered and such is wholly inoperable. The specification does not enable one of ordinary skill in the art to which it pertains, or with

which it is most nearly connected, to treat or prevent ALL possible retrovirals; inhibit retroviral replication; inhibit a protease of a retrovirus as presently claimed. Applicants' are invited to come in with a declaration utilizing the claimed composition demonstrating positive retroviral treatment and/or prevention; inhibiting retroviral replication; inhibiting a protease of a retrovirus.

Guidance and working examples: The specification describes the claimed compound of formula I and other compounds that may be combined with the compound. The tests at pages 15-20 of the specification are noted. It is not clear that the assay/test correlate to retroviral treatment and/or prevention. There is no evidence of functional treatment, i.e. no correlation to treatment in humans.

Moreover, it is not clear what the scope of 'infection or disease associated with retrovirus infection' is. It is not seen where applicants demonstrate the claimed composition effective in treating such. Further, applicants' are claiming all such infections or diseases know to associated with retrovirus infection and such as may be determined to be associated in the future and such is wholly inoperable.

Further, the specification does not teach how to prepare the ester, prodrug or metabolite of the compound of formula I. Nor have such forms been found to treat/prevent any retroviral; inhibit retroviral replication; inhibit a protease of a retrovirus as it pertains to ALL retroviruses as presently claimed by applicants'.

Also, it is noted that the ingredient/compound named to be combined with formula I are really *classes of compounds*. One of ordinary skill in the art would have to pick and choose a *specific* compound from among the *class of compounds*, combine them with formula I and then determine if said composition has antiretroviral activity. The skilled artisan would also need to

determine the ratio of each compound in the combination. Applicants have not provided ratios, dosages, modes of administration for all such combinations. Where is the direction and guidance? The classes of compounds encompass all compounds presently known and yet to be discovered and is wholly inoperable. Applicants' have not have enabled such future possibilities and cannot have protection for such.

Thus, the specification fails to provide sufficient support of the broad use of compound I in any form combined with other compounds/ingredients effective in treating/preventing retrovirals. As a result necessitating one of ordinary skill to perform an exhaustive search for how to prepare such compositions and then determine if they have the desired antiretroviral activity in order to practice the claimed invention.

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, one of ordinary skill in the art would have to engage in undue experimentation to test which forms of the compound of formula I can be prepared and their antiretroviral activity alone or in combination with other antiretroviral agents.

This rejection can be overcome by deleting the claims.

Claims 20,21,30,33,38,43,54,66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 reads 'of treating or treating' which is confusing. Please clarify/correct.

The claims contain the term 'prodrug' which is ambiguous and indefinite. Absent any definition or specific description and enablement, the killed person in the art was

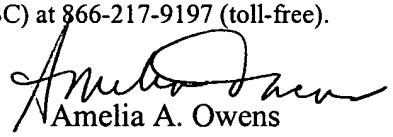
not offered any guidelines as to the meets and bounds of the scope being encompassed by the term. It is noted that a 'prodrug' can be derivatizing a functional group, time releasing formulation, etc., even those yet to be discovered prodrugs.

A terminal disclaimer was filed and accepted. Therefore, the double patenting rejection is dropped.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Amelia A. Owens
Primary Examiner
Art Unit 1625